UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF
PENNSYLVANIA

UNITED STATES OF AMERICA

ex rel. [UNDER SEAL],

Plaintiffs,

vs.

[UNDER SEAL],

Defendants.

Case No. 19-cv-3439

JURY TRIAL DEMANDED

QUI TAM FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729, *et seq.*

FILED UNDER SEAL
Pursuant to 31 U.S.C. § 3730(b)(2)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, STATE OF ALASKA, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA MEDICAL ASSISTANCE PROGRAMS, STATE OF MARYLAND, STATE OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, STATE OF VERMONT, STATE OF VIRGINIA, STATE OF WASHINGTON, STATE OF WISCONSIN,
ex rel.

DAVID NYBERG,

Plaintiff,

v.

ADVANCED BIONICS CORPORATION,

Defendant.

Case No. 19-cv-3439

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JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

1. Relator David Nyberg brings this action on behalf of himself, the United States of America, and the above named Plaintiff-States against Defendant Advanced Bionics Corporation for its violations of the federal False Claims Act ("federal FCA"), 31 U.S.C. §§ 3729 *et seq*., and of the above-named Plaintiff-States ("State FCAs") (collectively, the "False Claims Act").

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1331, 1345.

3. In accordance with 31 U.S.C. § 3730(e)(4), prior to filing this action, Relator has voluntarily disclosed to the Government the information on which the allegations or transactions raised herein are based.

4. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 31 U.S.C. § 3732(a), as Defendant transacts business in this jurisdiction and violations of the False Claims Act described herein occurred in this district.

GOVERNMENT HEALTHCARE PROGRAMS

5. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.,* establishes the Health Insurance for the Aged and Disabled Program, also known as Medicare. The United States Department of Health and Human Services ("HHS") administers the Medicare Program through the Centers for Medicare and Medicaid Services

("CMS").

6. The Medicare program is comprised of four parts. Medicare Part A provides basic insurance for the costs of hospitalization and post-hospitalization care. 42 U.S.C. §§ 1395c-i-5. Medicare Part B covers medical services and equipment such as outpatient care, medical supplies, and laboratory services. 42 U.S.C. §§ 1395j-w-5. Separate payments are made for each Current Procedures Terminology ("CPT") and Healthcare Common Procedure Coding System ("HCPCS") code listed on the Medicare Part B claims. *See* 45 C.F.R. §§ 162.1000, 162.1002, 162.1011, adopting the HCPCS as maintained and distributed by HHS, and the Current Procedural Terminology Coding Manual published by the American Medical Association (the "CPT Manual"). Medicare Part C, also known as Medicare Advantage, is a plan offered by private insurers that contract with Medicare to provide Part A and Part B benefits. 42 U.S.C. §§ 1395w-21-w-28. Medicare Part D is a plan offered by private insurers approved by Medicare to provide basic insurance for prescription drugs. 42 U.S.C. §§ 1395w-101-w-154.

7. Providers who wish to be eligible to obtain Medicare reimbursement must certify, *inter alia*, that they agree to comply with the Medicare laws, regulations and program instructions that apply to them, and that they acknowledge, *inter alia*, that payment of claims by Medicare is conditioned upon the claim and the underlying transaction complying with all applicable laws, regulations, and

program instructions. *See, e.g.,* Form CMS-855A (for institutional providers); Form CMS-855S, at 24 (for certain suppliers); Form CMS-855I (for physicians and non-physician practitioners).

8. Claims submitted by healthcare providers to Medicare contain similar representations and certifications. *See, e.g.,* Forms CMS-1500 (paper provider claim form; 837P (electronic version of form 1500); 1450 (UB04 – institutional provider paper claim form); 837I (electronic version of form 1450). When submitting a claim for payment, a provider does so subject to and under the terms of his certification to the United States that the services were delivered in accordance with federal law, including, for example, the relevant Medicare laws and regulations. Medicare requires compliance with these certifications as a material condition of payment, and claims that violate these certifications are false or fraudulent claims under the False Claims Act.

9. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.*, establishes the Medicaid program, a federally assisted grant program for the States. Medicaid enables the States to provide medical assistance and related services to needy individuals. CMS administers Medicaid on the federal level. Within broad federal rules, however, each state decides who is eligible for Medicaid, the services covered, payment levels for services and administrative and operational procedures.

10. At all times relevant to this Complaint, the United States provided funds to the States through the Medicaid program pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.* Enrolled providers of medical services to Medicaid recipients are eligible for payment for covered medical services under the provisions of Title XIX of the 1965 Amendments to the Federal Social Security Act.

11. TRICARE is a government-funded program that provides medical benefits to retired members of the Uniformed Services and to spouses and children of active duty, retired, and deceased members, as well as reservists who were ordered to active duty for thirty (30) days or longer. The program is administered by the Department of Defense and funded by the federal government.

12. Veterans of the United States military receive insurance benefits ("VA Insurance") through the Veterans Health Administration, a component of the U.S. Department of Veterans Affairs.

13. The Federal Employees Health Benefits Program ("FEHBP") provides healthcare benefits for qualified federal employees and their dependents. Under the FEHBP, the federal employee is covered by private payer health insurance which is in turn subsidized in part by the federal government.

14. The Office of Workers' Compensation Programs ("OWCP") of the U.S. Department of Labor ("DOL") administers federal workers' compensation

programs under four statutes: (1) the Federal Employees' Compensation Act ("FECA"), 5 U.S.C. §§ 8101 *et seq*.; (2) the Longshore and Harbor Workers' Compensation Act ("LHWCA"), 33 U.S.C. §§ 901 *et seq*.; (3) the Federal Black Lung Benefits Act ("FBLBA"), 30 U.S.C. §§ 901 *et seq*.; and (4) the Energy Employees Occupational Illness Compensation Program Act ("EEOIC") (also known as the "Beryllium Exposure Compensation Act"), 42 U.S.C. §§ 7384 *et seq*.

15. Together, the programs described above, and any other government-funded healthcare programs, are referred to herein as "Government Healthcare Programs."

16. Medicare, Medicaid, the Veteran's Administration and other public health care plans cover cochlear implants.

17. Each of the named Plaintiff-States offer Medicaid coverage for cochlear implants for children, and in some cases may cover adult cochlear implants as well.

PARTIES

18. Defendant Advanced Bionics Corporation ("AB") is a California corporation with its principal place of business at 28515 Westinghouse Place, Valencia, California 91355.

19. Relator Nyberg was AB's Principal RF Electrical Engineer R&D at the Valencia, California facility from December 2010 to August 2017.

FACTUAL ALLEGATIONS

Cochlear Implants

20. A cochlear implant ("CI") is an active prosthetic device implanted into a user's inner ear that stimulates the auditory nerve fiber bundles and thus restores or creates functional hearing.

21. Modern CIs all consist of the same basic functional units: an external unit, also known as the sound processor (or speech processor), which is made up of a digital signal processing ("DSP") unit and an RF transmitter; and an implanted, internal unit, which consists of the RF receiver and a hermetically-sealed stimulator, both of which are powered from the RF signal that comes from the external RF transmitter.

22. The RF signal is used to decode the data and convert it to electric currents, which are then delivered to electrodes placed in the cochlea of the user to simulate auditory signals.

23. The RF signal also provides power to the stimulator.

24. Thus, the RF component provides both the signal that transmits sound from the external to the internal unit, and the power that creates the electric current used to stimulate the auditory nerve fibers.

25. CIs are regulated by the Federal Communications Commission ("FCC") under Part 15, Radio Frequency Devices.

26. As active prosthetic devices, CIs are also governed by the Federal Food, Drug, and Cosmetic Act ("FDCA") as amended by the Medical Device

Amendments of 1976, the Safe Medical Device Act of 1990, and the Food and Drug Administration Modernization Act (FDAMA) of 1997.

Regulation of RF Frequency by the FCC

27. Under the regulatory scheme of the FCC, CIs are considered Class A digital devices, which is defined in 47 C.F.R. § 15.3 as a digital device marketed for use in a commercial, industrial or business environment, exclusive of a device which is marketed for use by the general public or is intended to be used in the home.

28. In or about August 2009, AB's devices were categorized as unintentional radiators of RF energy.

29. Under 47 C.F.R. § 15.3 (z), an unintentional radiator is a device that intentionally generates radio frequency energy for use within the device, or that sends radio frequency signals by conduction to associated equipment via connecting wiring, but which is not intended to emit RF energy by radiation or induction.

30. Based on this classification as an unintentional radiator, AB devices are exempt under Section 15.103(e) from complying with some specific technical standards, but remain subject to the general conditions of operation in Section 15.5.

31. In fact, when informing AB that its devices would be classified as unintentional radiators, the FCC explicitly noted that AB devices must continue to comply with Section 15.5, "particularly that they must not cause harmful

interference."

32. Harmful interference is defined in 47 C.F.R. § 15.3(m) as "[a]ny emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with this chapter."

33. The field strength of radiated emissions from a Class A digital device categorized as an unintentional radiator is set in § 15.109.

34. A CI will be considered compliant with FCC regulations if the CI "may be shown to comply with the standards contained in Third Edition of the International Special Committee on Radio Interference (CISPR), Pub. 22, 'Information Technology Equipment - Radio Disturbance Characteristics - Limits and Methods of Measurement' (incorporated by reference, *see* § 15.38)." § 15.109(g). This testing scheme is commonly referred to as CISPR-11.

35. The CIs manufactured by AB cannot pass CISPR-11 testing.

36. Despite the fact that its devices cannot pass CISPR-11 testing, AB has obtained passing test scores on CISPR laboratory tests by fraudulent means.

37. AB then submitted these fraudulent test results to the FDA and other entities, nationally and internationally, to obtain regulatory approval for its devices.

Regulation of Cochlear Implants by the FDA

38. The Medical Device Amendments of 1976 established three regulatory

categories for all medical devices.

39. The most regulated devices, which include cochlear implants, are in Class III. A Class III device is defined as one that supports or sustains human life, or is of substantial importance in preventing impairment of human health, or presents a potential, unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C)(ii).

40. To protect against these risks, Congress requires that Class III devices undergo an extensive premarket approval process. This process, established by the FDA pursuant to this Congressional delegation, sets forth the protocol for conducting clinical studies of cochlear implants to ensure that they are safe and effective for use in human patients.

41. Class III devices must also comply with the FDA's design control regulations, found at 21 C.F.R. § 820.30, which require the manufacturer to "establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met." *Id*. at (a)(1). This includes the requirement that the design be reviewed, verified, and validated (*id.* at §§ (e)-(g)).

42. As to validation, the FDA provides that:

> Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation,

> including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

43. As part of that pre-approval process, the device's RF components must undergo testing to ensure that it meets Radio Frequency Standards. This is because, as the FDA has noted:

> There has been rapid growth in medical devices that incorporate RF wireless technology due to the expansion of this technology. With the increasing use of RF wireless medical devices, continuing innovation and advancements in wireless technology, and an increasingly crowded RF environment, RF wireless technology considerations should be taken into account to help provide for the safe and effective use of these medical devices.

"Guidance on Radio Frequency Wireless Technology in Medical Devices," Section 3e.

44. Accordingly, "[a]s part of a comprehensive quality system under 21 C.F.R. Part 820, medical device manufacturers must manage risks including those associated with RF wireless technology that is incorporated into the medical device or device system." *Id*. at 6.

45. Risk management is "a key component of the quality system, and includes risk analysis, which is part of the design control requirements under the quality systems regulation." Such risks include poorly characterized or poorly utilized wireless systems as well as lost, corrupted, or time-delayed transmissions, and degradations in wireless transmissions, including degradation and delays caused by

competing wireless signals or electromagnetic interference (EMI).

46. Thus, in validating the design of a wireless medical device under 21 C.F.R. § 820.30(g)—a step necessary to receive FDA approval—the designer is required to include risk analysis of RF wireless communications and control functions. *Id*.

47. Designers are explicitly told to consider "risks to other devices and patients whose wireless connections might suffer from, or be the source of, interference. In addition, you should consider the potential impact of unintended interference and purposeful attempts to disrupt a wireless medical device or an associated device network's functionality." *Id*. at 7.

48. These same guidance materials contain specific recommendations with respect to choosing RF frequency and operations, noting that there is "a potential for interference in this frequency band because it is already heavily used by many other communications and industrial products." *Id*. at 8.

49. Designers are to consider, *inter alia*, applicable International Telecommunication Union Radio Communication Sector (ITU-R) recommendations and the impact of other users of the adjacent bands. *Id*.

50. Expanding further on this later requirement, in a section titled "Wireless coexistence," the FDA describes exactly the problem at issue here:

> A key factor affecting a wireless medical device's performance is the limited amount of RF spectrum available, which can result in potential competition among wireless technologies for simultaneous access to the same spectrum. Because conflicts among wireless signals can be expected,

most wireless communication technologies incorporate methods to manage these conflicts and minimize disruptions in the shared wireless environment. The selection of RF wireless operating frequency and modulation should take into account other RF wireless technologies and users that might be expected to be in the vicinity of the wireless medical device system. These other wireless systems can pose risks that could result in medical device signal loss or delay that should be considered in the risk management process.
Id. At 9.

51. With respect to devices, like CIs, that incorporate RF wireless technology, the FDA provides specific recommendations for Premarket Submissions (including premarket notifications, *de novo* petitions, and premarket approval applications).

52. For such devices, the FDA recommends including, in the description of the device, the specific RF frequencies used, the maximum output powers, and the range. *Id*. at 14-15. The FDA also recommends inclusion of "any risks and potential performance issues that might be associated with wireless coexistence in a shared wireless environment," suggesting that such should be addressed via testing and analysis with other wireless products or devices.

53. The Premarket Submission should include, *inter alia*, a summary of the coexistence testing, set-up, findings, and analysis; the interferers used and their frequencies, max output and separation distance from the device; the specific pass/fail criteria for the testing at issue; and how the device and wireless functions were monitored during the testing and determined to meet the pass/fail criteria. *Id*. at 15-16.

54. Testing information and results from the "final integrated product" are to be summarized in the Premarket Submission, which should include:

- Description of the tests performed (e.g., RF wireless performance, EMC immunity and emissions, test levels or limits) and the protocol used;
- Reference to appropriate medical device, RF wireless technology, or EMC standards for the tests;
- Explanations for any deviations from the selected standards;
- Mode(s) of device operation during testing, with an explanation of the significance of these modes;
- Specific pass/fail criteria for the testing such as specific device-related acceptability criteria for each device mode or function tested. These criteria should include the following:
  - Specific device functions that should not degrade (such as CPU failure);
  - Device functions that may degrade (such as display fluctuation); and
  - Device recovery from degradation (such as after removal of the electrostatic discharge (ESD)).
- If modifications were made to the medical device in order to pass testing, a statement that all modifications will be incorporated into all final production units.

Id. at 16-17 ("Test data summaries").

55. Advanced Bionics has voluntarily elected to include this information in its submissions to FDA and in doing so has made false representations about the testing of its devices.

Harmony (2006)

56. Although Relator was not employed at Advanced Bionics during the Premarket Submission for the Harmony, as a part of his work on the Neptune unit, he was provided with a summary of "Emission Test Results" prepared by his

predecessor, which had been presented to AB leadership on September 30, 2010 (the "September 2010 Presentation").

57. The September 2010 Presentation covers testing done as early as 2005, and had the stated objective to "[o]btain emissions compliance with margin sufficient to cover production variations for newly developed body worn processor (Neptune)".

58. In that September 2010 Presentation, Relator's predecessor admitted that emissions testing was "[h]istorically not met with previous body worn processors (Clarion, S-Series, PSP)."

59. The same slide noted that "TUV records show compliance with Harmony BTE (behind-the-ear) processor," a statement that was supported by a graph. The graph is from the official emissions test report, which Relator believes was performed at TUV in San Diego, CA on June 10, 2005, and purports to show a passing test score.

60. However, by the time of Relator's tenure, this June 2005 test had become a running joke among those involved in the AB emissions testing. As it was later explained to Relator by AB's Vice President of Regulatory Affairs, as well as by the Director of Engineering, the testing team took a Harmony sound processor to the test lab and the results were so bad that it was clear there was no way the unit would ever pass. Accordingly, the testing team engineers switched the unit into

"mic check mode," which completely turns off the RF transmitter.

61. Thus, the graph that is part of the September 2010 Presentation, which appears to indicate a passing score, and which on information and belief was submitted to the FDA, was obtained by turning the unit off.

62. Another slide in the September 2010 Presentation shows another test of the Harmony sound processor that was performed March 17, 2009. This test makes clear that even two years later, the Harmony processor was incapable of passing emission testing.

Neptune (approved 2011)

63. As noted above, the stated objective of the September 2010 meeting was to "[o]btain emissions compliance with margin sufficient to cover production variations for newly developed body worn processor (Neptune)." At that time, Relator's predecessor summarized work to date by stating that "Neptune evaluations have shown a narrow pass with one unit, but many overages and variability dependent on the accessory configuration."

64. The presentation openly acknowledged that there was little to be done about the processor, cable, and headpiece, stating that "[g]iven the fixed nature of the implanted device and the difficulty of attaining large improvements with the processor, cable and headpiece; [sic] attention has been devoted to reducing emissions by controlling the generated 49MHz fundamental and the test

configuration (within the rules of the CISPR test method)." A list of specific issues with the hardware that contribute to the problem included:

- High board-fill with components doesn't allow for top shield layer
- Vertical via map doesn't allow for complete vertical shielding and burying of hot traces
- Wire bonding, test pads, and test fixturing creates undesirable connects between top and bottom layers
- Open solenoid inductors
- Plastic enclosure provides no shielding nor isolation

65. In early October 2010, AB hired an outside consultant to review the design and identify easy and inexpensive steps to remedy the Neptune's emissions problems. His recommendations were shared first with Relator's predecessor and later with Relator, the new technical lead for the Neptune after fall 2010.

66. Unfortunately, none of the consultant's suggestions were able to solve the emissions issues for the Neptune.

67. Relator Nyberg began work at AB on December 13, 2010, as a contractor with a thirty-day trial engagement.

68. His first assignment was Technical Lead for the Neptune sound processor, and on that same day he requested from his direct supervisor the "written approved procedure for EMI testing" for the company.

69. Relator received a response from the Director of Engineering:

> There currently is no such procedure. EMI is not something that was a major concern before for our products, but the regulations have become tighter. It is not 100% clear to which extent which regulations apply, but CISPR-11 is one that we need to meet. …. The

> way CISPR-11 is written leaves some room for interpretation. Our interpretation is the one I briefly mentioned this morning where we would use non-radiating equivalents of the system components that are not part of the [Device Under Test] but are required to operate the [Device Under Test] in a normal fashion. For Neptune, for instance, this is the little aluminum box the machine shop is modifying for us, which will hold a reference implant and a headpiece with an "RF feedthrough" to the outside.
> We are going to need to formalize and approve an EMI test procedure that complies with the regulations we need to meet and that we adhere to internally, starting with Neptune and going forward for all future developments.

70. On Relator's second day at work, his supervisor expounded on this plan to use a "Test Box" (sometimes later called a "Reference Implant Box," and which internally became known as "Dave's Magic Boxes"). These Test Boxes were used to block RF emissions to ensure the device could pass CISPR testing.

71. His supervisor showed Relator a prototype Test Box on his second day.

72. This Test Box made it possible for the Neptune to pass testing, but it was not part of the production models of the Neptune. Therefore, the tests do not mirror the production environment at all.

73. Shortly after he was shown the prototype Test Box, Relator was formally given the responsibility to have the Neptune product pre-screened for emissions. Accordingly, he began to analyze whether the Neptune product would be able pass the CISPR-11 testing.

74. As Relator came up to speed, he saw several red flags. For example, he was told that the product was to be tested using a nine-inch RF cable, when normal use

would be up to 42 inches.

75. On December 17, 2010, Relator explained via email to the Director of Engineering, the Senior Manager of Regulatory Affairs, the Senior Program Manager, the Program Manager, and his own supervisor how the first RF emissions testing on the Neptune would be performed.

76. As he had been instructed, Relator's plan included use of the Test Box.

77. The team also had decided that the software would be used to command lowered operating conditions in order to get the design close to a passing test report.

78. The test plan was rife with caveats that the results will be "for engineering use only."

79. On December 22, 2010, Relator Nyberg wrote to the same group to report on the results of in-house testing he had performed.

80. Initial results led him to believe that "we have little to worry" with the testing. He tested the Neptune in various configurations, with and without the Test Box, in order to determine which was the best configuration to take to CKC labs.

81. On December 23, the Director of Engineering instructed Relator: "[t]o validate your setup further and understand where we are doing well [with respect to] emissions, you should also run some Harmony and PSP devices and take some measurements with a native ICS (not the test box)."

82. But later the same day, Relator realized that a crucial piece of test equipment he had been using was not providing valid data, and the Neptune emissions issue was therefore much worse than it had initially appeared.

83. He informed the group that "[w]e are failing and pretty hot too!" and in response, he received a reply from the Director of Engineering to only himself, instructing Relator to "please keep these emails narrowly distributed."

84. The first official RF emissions testing of the Neptune sound processor occurred on or about December 20 and 21, 2010 at CKC labs in La Brea, California. On December 23, Relator Nyberg wrote to the Director of Engineering explaining some of the settings used to get the best results possible, and that in spite of that effort, the unit still failed the test.

85. This email provoked a Christmas Eve response from the Director of Engineering, asking Relator to give him results for "Neptune with 9" cable (no programming or control header)."

86. Relator responded on Christmas Day, discussing what could be done to achieve a passing result and noting "I think I see where you're going with this...Shortest cable, lowest PWR setting, maybe we can get by. .."

87. From that point on, tweaking the testing conditions (rather than fixing the failure) were the main concern of everyone from Relator to top AB executives.

88. In an effort to figure out how to get the Neptune to pass, Relator took five

Neptune units for testing and discovered that the problem was a moving target. Some units fared better than others but only under carefully "doctored" test conditions.

89. Any Neptune unit tested using "real world" case conditions failed consistently, and quite badly if the longer coax cables were used.

90. In January 2011, Relator's trial period ended, and he was hired as a full-time employee.

91. On January 18, those expected to attend the "Neptune Core Team Meeting" the next day received an email, stating that "[t]he company needs to get Neptune to market now more than ever" and providing a list of "gating" issues that were holding up Premarket Submission.

92. In related conversations, it was suggested that to have any chance of getting Neptune through emissions testing, Relator would be required to screen dozens of units and select those with the lowest emissions signatures, based on the evidence discovered during the CKC labs test in late December.

93. This is memorialized in his response to the team email, in which Relator stated that "[b]ased on this list, I am prepared to go forward as long as I have access to enough units to screen. As soon as I have them, I will prescreen at AB, then verify at CKC. I will schedule CKC verification as soon as in house prescreen is complete. Only units that pass in house will go to CKC. Comments welcome."

94. For this "prescreen," Relator was given a bucket of approximately twenty-five prototype units. From those, he identified a single Neptune unit that had a much lower emission signature than any other unit manufactured. This low emission unit then became the single unit that he would take to the test labs (including later to China) for official passing test reports, all based on the "doctored" operating parameters.

95. These doctored parameters were not clearly stated in writing until much later, but eventually (in October 2013), Relator's supervisor laid out the practice of altering the sound processor under test in order to ensure that the hardware presented as little harmonic radiation as possible.

96. In providing an overview of AB's standard testing protocol, Relator's supervisor stated the following (emphasis added):

> - Obtain a **known good** Neptune for which **recent passing ATE data is available**
> …
> - Insert a fresh battery and start the process or from the battery, with no control header attached.
> - Verify the presence of stim on the channel that is brought out of the box.
> - Using BEPS, lower the RF level by 1, unlock/relock the implant, and keep doing this until the processor no longer relocks. **Record the last RF level the processor locked successfully, and use the ATE Neptune ATE datasheet to look up the RF power of that Neptune processor put out for that RF level**. Record the RF power. This will let us keep track of the minimum RF power that is required to lock to the implant in each box, and if that parameter were to shift between calibration cycles, we will see that. The acceptance limit for this particular test would be that the required

> power to lock shall not exceed the previously recorded RF power level by x% (20% perhaps?).

97. In other words, the practice was to turn down the RF power setting to as low as possible and use that as the test case.

98. This was the same method used throughout Relator's tenure at AB from January 2011 to August 2017 for both Neptune and Pantera/Naida devices, and at the time Relator left, it was anticipated that it would be applied to the new Coguaro design as well.

99. It appears that the Test Boxes, at least, were also used for testing with the CPI3 (a device used by clinicians to program the units).

100. A passing score generated by turning down the unit to this artificially low-level means that the majority of units operating in the field are violating RF interference limits, because the settings described above, which barely made the system work at all, do not resemble real-world therapy settings.

101. Over three days from March 2 to 4, 2011, Relator Nyberg personally took the single, hand-selected, Neptune sound processor to the TUV test lab near San Diego, CA, where he obtained a "passing" score for the unit.

102. To summarize, this passing score was obtained only by (a) hand-selecting the unit with the lowest (in fact, abnormally low) emission; (b) using the shielded Test Box; (c) using the shortest possible coax cable; and (d) using "doctored" specifications described above.

103. Relator Nyberg has personal knowledge that testing performed either without a Test Box or with a coax cable longer than 9 inches results in multiple harmonic failures.

104. In fact, even with all of this assistance, glaring issues remain. Review of the emissions results graph details show that the Neptune score fell within the margin of error the lab is able to certify. In other words, four of the harmonic emissions were technically under the limit line for failure, but were within the margin of error and so could easily have failed if the test was repeated.

105. After his return from the TUV test lab, Relator communicated his concern with the results to AB executive management, but was told that a passing report was "good enough."

106. ABA submitted the Premarket Submission to the FDA containing this fraudulently obtained result, and efforts at dealing with the Neptune's emissions profile temporarily cooled off.

107. In early February 2012, however, the Neptune issue heated up again when AB's VP of Regulatory Affairs informed Relator that China and South Korea had requested EMC testing samples of the Neptune design.

108. The VP was concerned as to whether the passing conditions Relator had created for the U.S. tests could be replicated overseas so that Neptune would still pass.

109. Accordingly, at the direction of his immediate supervisor and executive management, Relator was tasked with replicating the Test Boxes so that the emissions issues could be masked from these international testing entities.

110. The goal was to keep the level of harmonic emissions under the limit line for international testing (CISPR-11), which AB management knew could not be done without the shielding from the Test Boxes.

Pantera/Naida

111. As early as February 2011, a month before Neptune had "passed" its emissions testing, Relator Nyberg was asked to assist in what was then known as the "Pantera project," which later became the Naida line of behind-the-ear (BTE) sound processors (referred to herein as the "P/N" design).

112. The key focus for the P/N design team was to achieve significant reduction of the EM emissions signature over the older designs.

113. This effort failed, however, and as set out below, at the demand of AB management, Relator Nyberg obtained fraudulent "passing" test results for the Q30, Q70, and Q90 models of the Naida BTE processors, which were also submitted to the FDA.

114. In April 2011, the design team was struggling to get the wireless link (the Hi-BAN system, by Phonak) to work with the new Pantera sound processor due to interference from the main 49 MHz power and telemetry transmitter.

115. Specifically, the harmonics coming from the new main RF transmitter design was so overwhelming that the sensitive Hi-Ban system could not communicate with the MyPilot remote control products, which were also from Phonak.

116. Throughout the remainder of 2011, Relator participated in AB's ongoing efforts to solve this issue, including conferences with Phonak engineers. Ultimately a report on possible solutions was submitted to the Senior Director of Program Management (later Vice President of R&D), but none of the solutions were successful.

117. Internal work continued throughout the summer, but the team was no closer to a solution. In late August, AB consulted with Relator's predecessor, who again recommended using the same outside consultant.

118. In November 2011, AB's clinical engineer emailed the Director of Engineering to inform him of reports from Johns Hopkins, Henry Ford, and other hospital systems indicating that the Harmony BTE sound processor was causing Verizon cell phones to drop calls.

119. The same email acknowledged that AB has been aware of this issue since 2009 and had apparently replicated it in the lab.

120. The caller had questioned whether the problem would be addressed with the Harmony and future products.

121. The Director of Engineering forwarded this to Relator and his supervisor, and Relator was very concerned because he already knew that the problem would *not* be fixed in future products, because the Harmony design and the new P/N design were very similar, and the transmitter technology was nearly identical.

122. In December 2011, the first engineering samples of the new Pantera design were expected to arrive, but there were still concerns about RF emissions. The first in-house diagnostics showed failure, even with all of the "tricks" employed.

123. On May 24th, a Power Point presentation on performance issues with the P/N design effort to was sent to Relator, his supervisor, and the Director of Engineering, among others.

124. The cover email explained that AB's going-forward plan with respect to RF emissions: "[Relator] will take measurements on both BTE varieties and call me with the results tomorrow morning. If one BTE is significantly better than the other in terms of EMI testing, we will choose the layout with lower emissions. **If both pass EMI testing (ha!)** or there is no discernable difference we will choose the 090 due to the improved efficiency." (emphasis added).

125. On June 7, 2012, Relator drafted a summary of testing that lists the severe issues that were still being seen with P/N design. Emissions were still a grave concern in mid-June, and in mid-July, the water-proofing process (P2i) had a further negative effect on the emissions performance of the unit.

126. Later in July, Relator produced a second report on emissions for the P/N design.

127. He noted that, "[a]ll Advanced Bionics Sound Processors are required to comply with and pass CISPR11 RF levels for both emissions and susceptibility." He further detailed that, "[d]uring the design phase prior to V&V, Pantera was tested in-house using a calibrated 5402 GTEM cell from ETS Lindgren. It was realized at that point that the Pantera design suffered from excessive RF harmonic emissions. Suspicions were verified using calibrated measurements in the 10 meter anechoic chamber at TUV in San Diego."

128. Relator went on to show the "nearly 6 dBuV per meter margin" that had been obtained through the various mitigation suggestions, and included graphs showing this improvement.

129. Also in the mid-July timeframe, Relator began to obtain "official" emissions scans from Element Materials, an accredited lab in Irvine. While there, he took the opportunity to check emissions outside the test window and discovered that, just like the Harmony, the P/N design was likely to be a "cell phone call killer."

130. In October 2012, Relator performed a collection of "engineering scans" at the in-house test lab to evaluate how far out of compliance the P/N design was and what the best to be achieved would be. The results demonstrated that longer lengths of coax from the headpiece to the sound processor would not work, and

that without the Test Boxes, passing scores could only be achieved if the shortest cables were used and the sound processor was set to impossibly low power settings.

131. In December 2012, AB received its first formal testing for the P/N design at TUV labs in San Diego, CA. This formal report also appears to contain a passing test result. However, the harmonic emissions at 980 MHz (the twentieth harmonic) has ***zero*** margin, despite being conducted on a handpicked unit with its RF power turned as low as possible and the use of the Test Box. Given the parameters of certainty for the testing lab, this unit was very likely to fail if tested again.

132. Overall, this testing protocol (Test Box, short cables, low power settings) was successful until other countries started tightening their testing requirements. South Korea, Brazil and China were among the first to ask for units to be sent for testing.

133. In the case of South Korea and Brazil, AB was able to convince the testers to allow its engineers to "pre-program" the units so that they would be "properly programmed."

134. A December 2013 email from Relator's supervisor dealing with the South Korea testing lays out another tactic for faking a passing score that was dubbed "Fake Lock." This tool was developed for situations in which the foreign lab would not permit the use of the Test Boxes.

135. Fake Lock allowed AB to fool the sound processor into thinking it was working without the need for it to actually be locked to an implant, which normally would be required for operation. This, in turn, allowed AB to turn down the RF power to levels that wouldn't support normal system operation in any way.

136. RF power levels range from 0 to 15, with a control for standard power or double power, which was needed for patients who for some reason (*e.g.*, an unusually thick scalp) required a higher than usual power output in order to receive therapeutic benefits.

137. The P/N design can deliver as little as a few milliwatts up to about 110 milliwatts of RF power.

138. Typically, the minimum for basic therapy is in tens of milliwatts. With Fake Lock, that output could be turned down as low as needed to pass tests, well below the minimum needed to provide therapy. In fact, Fake Lock allowed the power to be turned below a few milliwatts – so low that the implant wouldn't even have enough power to turn on.

139. Unlike South Korea and Brazil, the Chinese CFDA did not allow pre-programming. Moreover, the test engineers wanted to test in a variety of configurations, some of which used "a fairly long cable," which panicked AB senior management and led to more end of December orders to test in the configurations being required by the Chinese testers.

140. Eventually, Relator, along with AB's Principal Embedded Software Engineer and Senior Manager of Production Integration, was sent to China in March 2017 to sit with the test technician and ensure the ruse continued to work.

141. An end of August 2014 report shows the methodology that was developed for achieving passing scores. This report shows that the unit was barely passing at the thirteenth harmonic of 637 MHz, with only .7dB/uV of margin, as opposed to the 6dB/uV below the limit line that is typically preferred in order to account for variability between test labs.

142. In January 2016, AB hired a new director for the Systems Department, filling a job that had been open for two years. As the new director began to come up to speed, he became concerned about the same issues Relator had been raising with respect to hiding RF problems rather than trying to solve them.

143. This new director asked that Relator come into the test lab at night and perform testing for his eyes only, in order to learn the true state of affairs. In March, two months after his arrival, the new director tasked Relator with drafting a definitive report on the true state of Pantera's emissions issues.

144. The new director asked that this report be provided to him only via thumb drive, and forbade Relator from using email to correspond about the project.

145. As the resulting presentation stated, "passing configuration for emissions testing of all 'Active' AB products is stringently 'choreographed' by compliance /

RF dept" and there was "[n]o passing configuration otherwise."

146. The presentation further warned that the "random testing promised by Chinese authorities" was a "huge business risk" and required a "constant ongoing effort" to keep the units passing by providing test rationales and "pre-programmed" tests, and that there were "Odd RF related reports from the field" that included cell phone and blue tooth issues.

147. Relator showed test results obtained as a result of the "choreography," pointing out that the results still had no margin, and highlighted the results against the European limits as well as the wi-fi, Bluetooth and cell phone bands to show the problems. Finally, Relator pointed out the increased issues with the use of even a 6-inch cable.

148. Despite these efforts, the next design after Pantera, the Conguaro line, exhibited the same issues.

149. By the time Relator was terminated, Coguaro had yet to be released. At the time of his termination, the design team was finding it difficult to get the new Bluetooth module to work with Coguaro because of the device's own RF harmonic emissions issues.

150. In June 2016, two months after presenting the report to the new director, the new director left AB and Relator was transferred within AB from Electrical Engineering to Design Assurance. In his new role, he was to be the local expert for

electrical compliance and to assist the design teams in testing and analysis.

151. In March 2017, Relator and colleagues again traveled to Beijing in order to shepherd the Naida Q30, Q70 and Q90 through Chinese testing.

COUNT I
VIOLATION OF 31 U.S.C. § 3729 - FALSE CLAIMS ACT

152. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

153. As set forth above, Defendant knowingly presented, or caused to be presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

154. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to numerous false claims, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

155. Due to Defendant's conduct, the Government has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. 31 U.S.C. § 3729.

156. Relator is entitled to a reasonable attorney's fees and costs, pursuant to 31 U.S.C. § 3730(d)(1).

COUNT II
VIOLATIONS OF 2016 ALASKA SESS. LAWS CH. 25 (S.B. 74) § 09.58.010 - ALASKA MEDICAL ASSISTANCE FALSE CLAIMS AND REPORTING ACT

157. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

158. As set forth above, Defendant knowingly presented or caused to be presented to the Alaska Medicaid program false or fraudulent claims for payment or approval, in violation of AK Stat § 09.58.010(a)(1).

159. As set forth above, Defendant knowingly made, used, or caused to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim for payment paid or approved by the state under the medical assistance program, in violation of AK Stat § 09.58.010(a)(2).

160. Due to Defendant's conduct, the state of Alaska has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. AK Stat § 09.58.010(c).

161. Relator is entitled to reasonable attorneys' fees, costs, and expenses. AK Stat § 09.58.010(c)(3).

COUNT III
VIOLATION OF CALIFORNIA GOVERNMENT CODE SECTION 12651 - CALIFORNIA FALSE CLAIMS ACT

162. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

163. As set forth above, Defendant knowingly presented or caused to be

presented to the California Medicaid program false or fraudulent claims for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).

164. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Cal. Gov't Code § 12651(a)(2).

165. Due to Defendant's conduct, the state of California has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Cal. Gov't Code § 12651(a).

166. Relator is entitled to reasonable attorneys' fees, costs, and expenses. Cal. Gov't Code § 12652(g).

COUNT IV
VIOLATIONS OF COLORADO REVISED STATUTE § 25.5-4-305 - COLORADO MEDICAID FALSE CLAIMS ACT

167. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

168. As set forth above, Defendant knowingly presented or caused to be presented to the Colorado Medicaid program false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(1)(a).

169. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Colo. Rev. Stat. § 25.5-4-305(1)(b).

170. Due to Defendant's conduct, the State of Colorado has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Colo. Rev. Stat. § 25.5-4-305(1).

171. Relator is entitled to reasonable attorney's fees, costs, and expenses. Colo. Rev. Stat. § 25.5-4-306(4).

COUNT V
VIOLATIONS OF CONNECTICUT GENERAL STATUTES § 4-274 et seq. – CONNECTICUT FALSE CLAIMS ACT FOR MEDICAL ASSISTANCE PROGRAMS

172. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

173. As set forth above, Defendant knowingly presented or caused to be presented to the Connecticut Medicaid program false or fraudulent claims for payment or approval, in violation of Conn. Gen. Stat. § 4-275(a)(1).

174. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Conn. Gen. Stat. § 4-275(a)(2).

175. Due to Defendant's conduct, the State of Connecticut has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Conn. Gen. Stat. § 4-275(a).

176. Relator is entitled to reasonable attorneys' fees, costs, and expenses. Conn. Gen. Stat. § 4-278.

COUNT VI
VIOLATIONS OF DELAWARE CODE TITLE 6, § 12-1201 - DELAWARE FALSE CLAIMS AND REPORTING ACT

177. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

178. As set forth above, Defendant knowingly presented or caused to be presented to the Delaware Medicaid program false or fraudulent claims for payment or approval, in violation of Del. Code Tit. 6, § 12-1201(a)(1).

179. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Del. Code Tit. 6, § 12-1201(a)(2).

180. Due to Defendant's conduct, the State of Delaware has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Del. Code Tit. 6, § 12-1201(a).

181. Relator is entitled to reasonable attorney's fees, costs, and expenses pursuant to Del. Code Tit. 6, § 12-1205.

COUNT VII
VIOLATIONS OF DISTRICT OF COLUMBIA CODE § 2-308.02 – DISTRICT OF COLUMBIA FALSE CLAIMS ACT

182. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

183. As set forth above, Defendant knowingly presented or caused to be

presented to the District of Columbia Medicaid program false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-308.02(a)(1).

184. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of D.C. Code § 2-308.02(a)(2).

185. Due to Defendant's conduct, the District of Columbia has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. D.C. Code § 2-308.14(a).

186. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to D.C. Code § 2-381.03(f).

COUNT VIII
VIOLATIONS OF FLORIDA STATUTE § 68.082 – FLORIDA FALSE CLAIMS ACT

187. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

188. As set forth above, Defendant knowingly presented or caused to be presented to the Florida Medicaid program false or fraudulent claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

189. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Fla. Stat. § 68.082(2)(b).

190. Due to Defendant's conduct, the State of Florida has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Fla. Stat. § 68.082(2).

191. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Fla. Stat. § 68.085.

COUNT IX
VIOLATIONS OF O.C.G.A. § 49-4-168.1 - GEORGIA FALSE MEDICAID CLAIMS ACT

192. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

193. As set forth above, Defendant knowingly presented or caused to be presented to the Georgia Medicaid program false or fraudulent claims for payment or approval, in violation of O.C.G.A. § 49-4-168.1(a)(1).

194. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of O.C.G.A. § 49-4-168.1(a)(2).

195. Due to Defendant's conduct, the State of Georgia has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. O.C.G.A. § 49-4-168.1.

196. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to O.C.G.A. § 49-4-168.2(i).

COUNT X
VIOLATIONS OF HAWAII REVISED STATUTES § 661-21 - HAWAII FALSE CLAIMS ACT

197. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

198. As set forth above, Defendant knowingly presented or caused to be presented to the Hawaii Medicaid program false or fraudulent claims for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(1).

199. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Haw. Rev. Stat. § 661-21(a)(2).

200. Due to Defendant's conduct, the State of Hawaii has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Haw. Rev. Stat. § 661-21(a).

201. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Haw. Rev. Stat. § 661-27.

COUNT XI
VIOLATIONS OF 740 ILLINOIS COMPILED STATUTES § 175/3 – ILLINOIS FALSE CLAIMS ACT

202. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

203. As set forth above, Defendant knowingly presented or caused to be

presented to the Illinois Medicaid program false or fraudulent claims for payment or approval, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1)(A).

204. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Ill. Comp. Stat. § 175/3(a)(1)(B).

205. Due to Defendant's conduct, the State of Illinois has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Ill. Comp. Stat. § 175/3(a)(1).

206. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Ill. Comp. Stat. § 175/4(d)(1).

COUNT XII
VIOLATIONS OF INDIANA CODE § 5-11-5.5-2 – INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

207. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

208. As set forth above, Defendant knowingly presented or caused to be presented to the Indiana Medicaid program false or fraudulent claims for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(1).

209. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements to obtain payment or approval of a false claim from the state, in violation of Ind. Code § 5-11-5.5-2(b)(2).

210. Due to Defendant's conduct, the State of Indiana has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Ind. Code § 5-11-5.5-2(b).

211. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Ind. Code § 5-11-5.5-6(a).

COUNT XIII
VIOLATIONS OF IOWA CODE § 685 – IOWA FALSE CLAIMS ACT

212. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

213. As set forth above, Defendant knowingly presented or caused to be presented to the Iowa Medicaid program false or fraudulent claims for payment or approval, in violation of Iowa Code § 685.2(1)(a).

214. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Iowa Code § 685.2(1)(b).

215. Due to Defendant's conduct, the State of Iowa has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Iowa Code § 685.2(1).

216. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Iowa Code § 685.3(4)(a).

COUNT XIV

VIOLATIONS OF LOUISIANA REVISED STATUTES ANNOTATED § 46:438.3 – MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

217. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

218. As set forth above, Defendant knowingly presented or caused to be presented to the Louisiana Medical Assistance Program false or fraudulent claims for payment or approval, in violation of La. Rev. Stat. Ann. § 46:438.3(A).

219. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of La. Rev. Stat. Ann. § 46:438.3(B).

220. Due to Defendant's conduct, the State of Louisiana has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. La. Rev. Stat. Ann. § 46:438.6.

221. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to La. Rev. Stat. Ann. § 46:438.6(D).

COUNT XV
VIOLATIONS OF MARYLAND CODE ANNOTATED § 2-602 – MARYLAND FALSE HEALTH CLAIMS ACT

222. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

223. As set forth above, Defendant knowingly presented or caused to be

presented to the Maryland Medicaid program false or fraudulent claims for payment or approval, in violation of Md. Code Ann. § 2-602(a)(1).

224. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Md. Code Ann. § 2-602(a)(2).

225. As set forth above, Defendant knowingly made other false or fraudulent claims against a State health plan or a State health program, in violation of Md. Code Ann. § 2-602(a)(9).

226. Due to Defendant's conduct, the State of Maryland has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Md. Code Ann. § 2-602(b)(1).

227. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Md. Code Ann. § 2-603(b)(2)(ii) and § 2-605(a).

COUNT XVI
VIOLATIONS OF MASSACHUSETTS GENERAL LAW ch. 12, § 5 – MASSACHUSETTS FALSE CLAIMS ACT

228. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

229. As set forth above, Defendant knowingly presented or caused to be

presented to the Massachusetts Medicaid program false or fraudulent claims for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(a)(1).

230. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Mass. Gen. Laws ch. 12 § 5B(a)(2).

231. Due to Defendant's conduct, the State of Massachusetts has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Mass. Gen. Laws ch. 12 § 5B(a).

232. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Mass. Gen. Laws ch. 12 § 5F.

COUNT XVII
VIOLATIONS OF MICHIGAN COMPILED LAWS 400.601 et seq. – MICHIGAN MEDICAID FALSE CLAIMS ACT

233. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

234. As set forth above, Defendant knowingly presented or caused to be presented to the Michigan Medicaid program false or fraudulent claims for payment or approval, in violation of Mich. Comp. Laws 400.607.

235. As set forth above, Defendant conspired to commit a violation of the Michigan Medicaid False Claims Act, in violation of Mich. Comp. Laws 400.606.

236. Due to Defendant's conduct, the State of Michigan has suffered substantial

monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Mich. Comp. Laws 400.612(1), an amount that will be proven at trial.

237. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Mich. Comp. Laws 400.610a(9).

COUNT XVIII
VIOLATIONS OF MINNESOTA STATUTE § 15C.02 – MINNESOTA FALSE CLAIMS ACT

238. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

239. As set forth above, Defendant knowingly presented or caused to be presented to the Minnesota Medicaid program false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

240. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Minn. Stat. § 15C.02(a)(2).

241. Due to Defendant's conduct, the State of Minnesota has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Minn. Stat. § 15C.02(a).

242. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Minn. Stat. § 15C.12.

COUNT XIX
VIOLATIONS OF MONTANA CODE ANNOTATED § 17-8-401 – MONTANA FALSE CLAIMS ACT

243. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

244. As set forth above, Defendant knowingly presented or caused to be presented to the Montana Medicaid program false or fraudulent claims for payment or approval, in violation of Mont. Code Ann. § 17-8-403(1)(a).

245. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Mont. Code Ann. § 17-8-403(1)(b).

246. Due to Defendant's conduct, the State of Montana has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Mont. Code Ann. § 17-8-403(1).

247. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Mont. Code Ann. § 17-8-410(3).

COUNT XX
VIOLATIONS OF NEVADA REVISED STATUTE ANNOTATED § 357.040 – SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT

248. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

249. As set forth above, Defendant knowingly presented or caused to be

presented to the Nevada Medicaid program false or fraudulent claims for payment or approval, in violation of Nev. Rev. Stat. Ann. § 357.040(1)(a).

250. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Nev. Rev. Stat. Ann. § 357.040(1)(b).

251. Due to Defendant's conduct, the State of Nevada has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Nev. Rev. Stat. Ann. § 357.040(2).

252. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Nev. Rev. Stat. Ann. § 357.180.

COUNT XXI
VIOLATIONS OF NEW JERSEY REVISED STATUTE § 2A:32C-3 – NEW JERSEY FALSE CLAIMS ACT

253. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

254. As set forth above, Defendant knowingly presented or caused to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval, in violation of N.J. Rev. Stat. § 2A:32C-3(a).

255. As set forth above, Defendant knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or

approved by the State, in violation of N.J. Rev. Stat. § 2A:32C-3(b).

256. Due to Defendant's conduct, the State of New Jersey has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. N.J. Rev. Stat. § 2A:32C-3.

257. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to N.J. Rev. Stat. § 2A:32C-8.

COUNT XXII
VIOLATIONS OF NEW MEXICO STATUTE § 27-14-2 – NEW MEXICO MEDICAID FALSE CLAIMS ACT

258. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

259. As set forth above, Defendant knowingly presented or caused to be presented to the New Mexico Medicaid program false or fraudulent claims for payment or approval, in violation of N.M. Stat. § 27-14-4(A).

260. As set forth above, Defendant knowingly presented or caused to be presented to the state a claim for payment under the medicaid program knowing that the person receiving a medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program, in violation of N.M. Stat. § 27-14-4(B).

261. As set forth above, Defendant knowingly made, used or caused to be made or used a record or statement to obtain a false or fraudulent claim under the

medicaid program paid for or approved by the state knowing such record or statement is false, in violation of N.M. Stat. § 27-14-4(C).

262. Due to Defendant's conduct, the State of New Mexico has suffered substantial monetary damages and is entitled to recover treble damages. N.M. Stat. § 27-14-4.

263. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to N.M. Stat. § 27-14-9.

COUNT XXIII
VIOLATIONS OF NEW MEXICO STATUTE § 44-9-3 – NEW MEXICO FRAUD AGAINST TAXPAYERS ACT

264. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

265. As set forth above, Defendant knowingly presented or caused to be presented to the New Mexico Medicaid program false or fraudulent claims for payment or approval, in violation of N.M. Stat. § 44-9-3(A)(1).

266. As set forth above, Defendant knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State, in violation of N.M. Stat. § 44-9-3(A)(2).

267. Due to Defendant's conduct, the State of New Mexico has suffered substantial monetary damages and is entitled to treble damages and a civil penalty for each false claim, record, or statement. N.M. Stat. § 44-9-3C.

268. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to N.M. Stat. § 44-9-7.

COUNT XXIV
VIOLATIONS OF NEW YORK UNIFORM COMMERCIAL CODE LAW § 189 – NEW YORK FALSE CLAIMS ACT

269. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

270. As set forth above, Defendant knowingly presented or caused to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval, in violation of N.Y. U.C.C. Law § 189(1)(a).

271. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of N.Y. U.C.C. Law § 189(1)(b).

272. Due to Defendant's conduct, the State of New York has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. N.Y. U.C.C. Law § 189(1).

273. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to N.Y. U.C.C. Law § 190(6).

COUNT XXV
VIOLATIONS OF NORTH CAROLINA GENERAL STATUTE § 1-607 – NORTH CAROLINA FALSE CLAIMS ACT

274. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

275. As set forth above, Defendant knowingly presented or caused to be presented to the North Carolina Medicaid program false or fraudulent claims for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).

276. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

277. Due to Defendant's conduct, the State of North Carolina has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. N.C. Gen. Stat. § 1-607(a).

278. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to N.C. Gen. Stat. § 1-610.

COUNT XXVI
VIOLATIONS OF OKLAHOMA STATUTE TITLE 63, § 5053.1 – OKLAHOMA MEDICAID FALSE CLAIMS ACT

279. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

280. As set forth above, Defendant knowingly presented or caused to be

presented to the Oklahoma Medicaid program false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

281. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements to get a false or fraudulent claim paid or approved by the state, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).

282. Due to Defendant's conduct, the State of Oklahoma has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Okla. Stat. tit. 63, § 5053.1(B).

283. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Okla. Stat. tit. 63, § 5053.4.

COUNT XXVII
VIOLATIONS OF RHODE ISLAND GENERAL LAWS § 9-1.1-3 – RHODE ISLAND FALSE CLAIMS ACT

284. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

285. As set forth above, Defendant knowingly presented or caused to be presented to the Rhode Island Medicaid program false or fraudulent claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

286. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

287. Due to Defendant's conduct, the State of Rhode Island has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. R.I. Gen. Laws § 9-1.1-3(a).

288. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to R.I. Gen. Laws § 9-1.1-4(d).

COUNT XXVIII
VIOLATIONS OF TENNESSEE CODE ANNOTATED § 71-5-182 – TENNESSEE MEDICAID FALSE CLAIMS ACT

289. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

290. As set forth above, Defendant knowingly presented or caused to be presented to the Tennessee Medicaid program false or fraudulent claims for payment or approval, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

291. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

292. Due to Defendant's conduct, the State of Tennessee has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Tenn. Code Ann. § 71-5-182(a).

293. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Tenn. Code Ann. § 71-5-183(d).

COUNT XXIX
VIOLATIONS OF TEXAS CODE § 36.002 – TEXAS MEDICAID FRAUD PREVENTION ACT

294. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

295. As set forth above, Defendant knowingly made or caused to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized, in violation of Tex. Code § 36.002(1).

296. As set forth above, Defendant knowingly made, caused to be made, induced, or sought to induce the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program, in violation of Tex. Code § 36.002(4)(B).

297. As set forth above, Defendant knowingly or intentionally charged, solicited, accepted, or received, in addition to an amount paid under the Medicaid program, a gift, money, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient where the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program, in violation of Tex. Code § 36.002(5).

298. As set forth above, Defendant knowingly engaged in conduct that constitutes

a violation of Tex. Code § 32.039(b), thus also violating Tex. Code. § 36.002(13).

299. The State of Texas is entitled to three times the amount of any payment or the value of any monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful act, including any payment made to a third party. Tex. Code §§ 36.052(a)(1) and 36.052(a)(4).

300. The State of Texas is entitled to prejudgment interest on the amount of the payment or the value of the benefit described in the above paragraph at the prejudgment interest rate in effect on the day the payment or benefit was received or paid, for the period from the date the benefit was received or paid to the date that the state recovers the amount of the payment or value of the benefit.

301. The State of Texas is entitled to a civil penalty as required by Tex. Code § 36.052(a)(3)(B) for each unlawful act committed by Defendant.

302. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Tex. Code § 36.110.

COUNT XXX
VIOLATIONS OF VERMONT STATUTE ANNOTATED § 631 – VERMONT FALSE CLAIMS ACT

303. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

304. As set forth above, Defendant knowingly presented or caused to be presented to the Vermont Medicaid program false or fraudulent claims for payment

or approval, in violation of Vt. Stat. Ann. § 631(a)(1).

305. As set forth above, Defendant knowingly presented or caused to be presented to the Tennessee Medicaid program false or fraudulent claims for payment or approval, in violation of Vt. Stat. Ann. § 631(a)(2).

306. Due to Defendant's conduct, the State of Vermont has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Vt. Stat. Ann. § 631(b).

307. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Vt. Stat. Ann. § 635(c).

COUNT XXXI
VIOLATIONS OF VIRGINIA CODE ANNOTATED § 8.01-216.3 – VIRGINIA FRAUD AGAINST TAXPAYERS ACT

308. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

309. As set forth above, Defendant knowingly presented or caused to be presented to the Virginia Medicaid program false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

310. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

311. Due to Defendant's conduct, the State of Virginia has suffered substantial

monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Va. Code Ann. § 8.01-216.3(A).

312. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Va. Code Ann. § 8.01-216.7.

COUNT XXXII
VIOLATIONS OF WASHINGTON REVISED CODE § 74.66.020 – WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT

313. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

314. As set forth above, Defendant knowingly presented or caused to be presented to the Washington Medicaid program false or fraudulent claims for payment or approval, in violation of Wash. Rev. Code § 74.66.020(1)(a).

315. As set forth above, Defendant knowingly made, used, or caused to be made or used, false records or statements material to false claims, in violation of Wash. Rev. Code § 74.66.020(1)(b).

316. Due to Defendant's conduct, the State of Washington has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Wash. Rev. Code § 74.66.020(1).

317. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Wash. Rev. Code § 74.66.070.

COUNT XXXIII
VIOLATIONS OF WISCONSIN STATUTES ANNOTATED § 20.931 – WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW

318. Relator hereby incorporates and realleges herein all other paragraphs as if full set forth herein.

319. As set forth above, Defendant knowingly presented, or caused to be presented to the Wisconsin Medicaid program numerous false or fraudulent claims for payment or approval, in violation of Wis. Stat. Ann. § 20.931(2)(a).

320. As set forth above, Defendant knowingly presented or caused to be presented to the Wisconsin Medicaid program false or fraudulent claims for payment or approval, in violation of Wis. Stat. Ann. § 20.931(2)(b).

321. Due to Defendant's conduct, the State of Wisconsin has suffered substantial monetary damages and is entitled to recover treble damages and a civil penalty for each false claim, record, or statement. Wis. Stat. Ann. § 20.931(2).

322. Relator is entitled to reasonable attorneys' fees, costs, and expenses pursuant to Wis. Stat. Ann. § 20.931(11).

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment:

(a) awarding the United States treble damages sustained by it for each of the false claims;

(b) awarding the United States the maximum civil penalty for each false claim;

(c) awarding the Plaintiff-States treble damages sustained by it for each of the false claims;

(d) awarding the Plaintiff-States the maximum civil penalty for each of the false claims;

(e) awarding Relator 30% of the proceeds of this action and any alternate remedy or the settlement of any such claim;

(f) awarding Relator litigation costs and reasonable attorney's fees; and

(g) granting such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Relator hereby respectfully demands trial by jury on all issues and counts triable as of right before a jury.

Respectfully submitted,

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